CORRELATION OF GASTRO ESOPHAGEAL VALVE, SYMPTOMATOLOGY AND 24 HOUR pH MONITORING IN GERD PATIENTS WITH REFRACTORY SYMPTOMS IN SOUTH INDIA – A CROSS SECTIONAL STUDY

Dissertation submitted in partial fulfillment of requirements for

DM DEGREE IN MEDICAL GASTROENTEROLOGY

BRANCH IV

Of

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MADRAS MEDICAL COLLEGE,
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CERTIFICATE

This is to certify that the dissertation entitled **"CORRELATION OF GASTRO ESOPHAGEAL VALVE, SYMPTOMATOLOGY AND 24 HOUR pH MONITORING IN GERD PATIENTS WITH REFRACTORY SYMPTOMS IN SOUTH INDIA – A CROSS SECTIONAL STUDY"** is a bonafide work done by **Dr. G.RAJESHKUMAR** at Madras Medical College, Chennai in partial fulfillment of the university rules and regulations for award of D.M., Degree in Medical Gastroenterology (Branch-IV) under my guidance and supervision during the academic year 2011 -2014.

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DECLARATION

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CORRELATION OF GASTRO ESOPHAGEAL VALVE, SYMPTOMATOLOGY AND 24 HOUR pH MONITORING IN GERD PATIENTS WITH REFRACTORY SYMPTOMS IN SOUTH INDIA – A CROSS SECTIONAL STUDY

ABSTRACT:

Aim of the study: This study was conducted to identify the grades of gastro esophageal valve (GEV) in gastro esophageal reflux disease (GERD) patients with refractory symptoms and to correlate the grades of GEV with 24 hour pH monitoring findings.

Methods: 30 patients with symptoms of GERD inspite of proton pump inhibitor therapy (omeprazole 20mg, twice daily) for 4 weeks were studied in Rajiv Gandhi general hospital, madras medical college, Chennai-3

Results: This study revealed higher grade of gastro esophageal valve(grade 3 & grade 4) had abnormal acid reflux evidenced by 24 hour pH monitoring (percent of time pH < 4, Demeester score) than grade 1 & grade 2 GEV. Patients with grade 3& grade 4 GEV had more incidences of distal esophagitis than grade 1 & grade 2.

Conclusion: Presence of abnormal gastro esophageal valves which are detected by retro flexion of upper GI endoscopy may predict the positive esophageal acid exposure and complication such as erosive esophagitis.

INTRODUCTION

Gastro Esophageal Reflux Disease (GERD) is a most commonly encountered problem in day today practice. It result from failure of the anti reflux barrier which expose esophageal mucosa to abnormal acid reflux / GER (Gastro Esophageal Reflux) which in turn results variety of symptoms such as heartburn, odynophagia, hoarseness of voice, Increased mucus in the throat, foreign body sensation of throat or *globus,* water brash, and many atypical symptoms such as chronic cough, recurrent sore throat and asthma if long standing.

Behind liver disease, it was considered the costlier GI disease with ranking second in 2004 with the prevalence rate in general population varies between 42% to 45% and 24% of the population will experience heartburn daily or more often.

In spite of effective treatment, around 20–40% of patients showed partial or lack of response to medical therapy that are labeled as refractory GERD and these set of patient are difficult to treat.

It is caused by a failure of the anti reflux barrier (ARB). Gastro esophageal valve (GEV) is one of the components of it. Alteration of this valve which in turn alters of lower esophageal sphincter length and pressure which results mechanically defective sphincter.

Esophageal acid exposure is directly proportional to the degree of gastro esophageal valve geometry. Reinforcement of the GEV by means of endoscopic methods or surgery may improve the symptoms in these patients with refractory symptoms.

Our present study was design to identify the type of gastro esophageal valve in GERD patients with refractory symptoms and correlation of symptoms and 24 hour pH monitoring findings.

AIM AND OBJECTIVES

I. To identify the grades of Gastro esophageal valve (GEV).

II. To study the symptomatology and 24 hour pH monitoring in GERD patients with refractory symptoms.

III. To study the correlation with GEV types with symptomatology and 24 hour pH monitoring in GERD patients with refractory symptoms.

REVIEW OF LITERATURE:

GERD is a most commonly encountered gastro intestinal disorder which has a significance recurrence rate with increasing in frequency of its incidence. According to the Gallup Organization whom they conducted a nationwide population-based study in the United States, 44% of the general population reported heartburn at least once a month.[1]

Montreal definition for gastro esophageal reflux syndrome[2]

Oesophageal syndromes	Extra-oesophageal syndromes established associations
Oesophageal symptomatic syndromes	Reflux cough syndrome
Typical reflux syndrome	Reflux asthma syndrome
Reflux/chest pain syndrome	Reflux laryngitis syndrome
	Reflux dental erosion syndrome
Syndromes with oesophageal injury	Proposed associations
Reflux oesophagitis	Pharyngitis
Reflux stricture	Sinusitis
Barrett's oesophagus	Recurrent otitis media
Oesophageal adenocarcinoma	Idiopathic pulmonary fibrosis

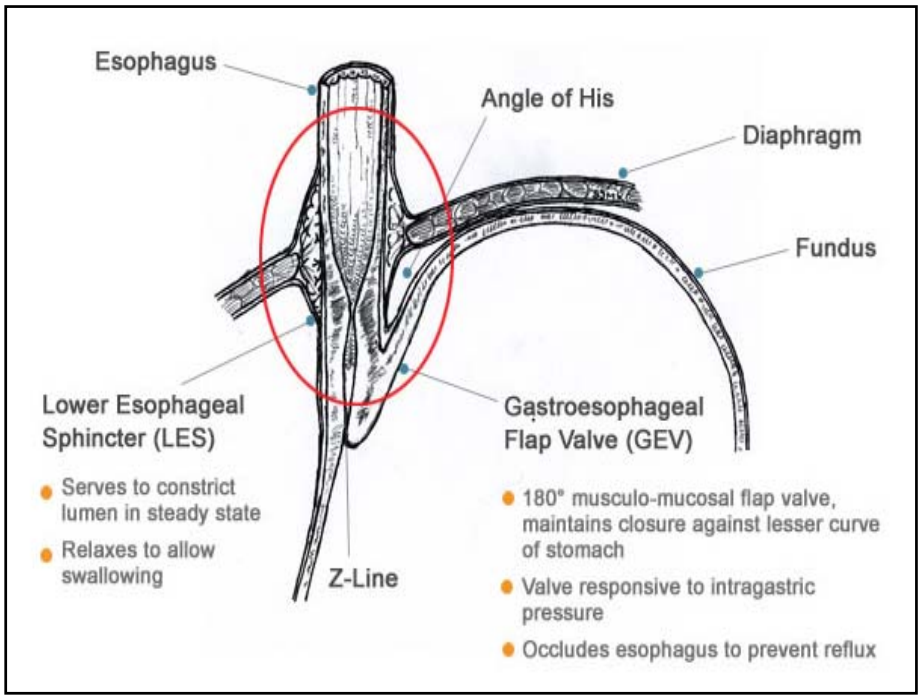
Even though it considered milder disease with almost nil mortality, it may result significant morbidity, such as 5% of the patients may develop esophageal ulceration, 4% to 20% develop peptic stricture and 8% to 20% develop Barrett's esopHagus.[3]

Proton pump inhibitors (PPIs) are considered safe and effective. Compared to H2-blockers, PPIs offer the best healing rates in patients with erosive esophagitis.

Most of the patients PPIs offer adequate relief within 2–4 weeks of therapy. In spite of effective treatment, around 20–40% of patients showed partial or lack of response to medical therapy that are labeled as refractory GERD and these set of patient are difficult to treat. [4]

It is caused by a failure of the anti reflux barrier (ARB). The components of antireflux barrier include Gastro esophageal valve (GEV), lower esophageal sphincter, acute angle of His, Intra-abdominal location of the LES, Diaphragmatic crura and Phreno esophageal ligaments.[5]

Components of ARB



In these patients, Upper gastro intestinal endoscopy is useful for evaluating mucosal integrity in patients with warning symptoms and complication such as esophageal stricture formation and Barrett's esophagus.

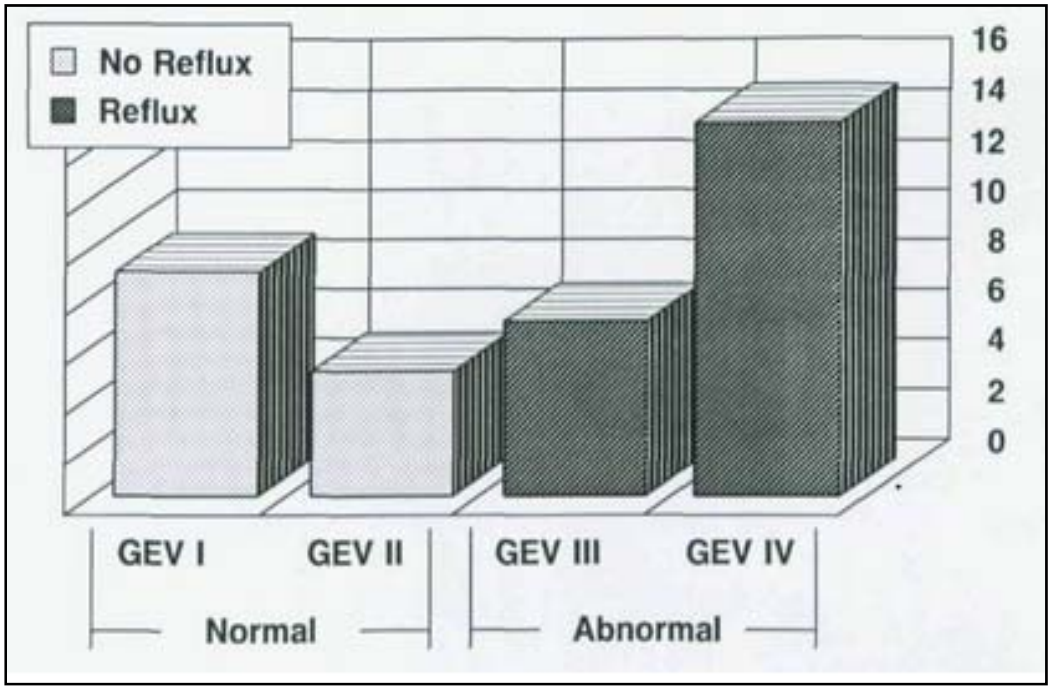
Edema and erythema are considered early endoscopic sign. Erosions usually begin at tops of mucosal folds at the OG (esophago gastric) junction whom labeled as distal esophagitis. Distal esophagitis are classified as grade A, B, C and D according to Los Angeles classification.[6]

Gastro esophageal valve (GEV) is an intra gastric musculo-mucosal fold, created by the angle of entry of the esophagus into the stomach. In the normal subject, it adheres to the endoscope through all phases of respiration. [7, 8, 9]

With a retroflexed endoscope, the valves are examined and classified 4 grades (Hill classification). Grade I, prominent fold which closely adherent the endoscope with orientation towards the lesser curvature which closes in all phases of respiration; grade II, less well prominent than grade 1which occasionally opens with respiration; grade III, no defined tissue around the endoscope which not closes during respiration; grade IV, always associated with hiatal hernia with no fold where esophageal lumen seen from the fundus. [7, 8, 9]

The grade of GEV is directly proportional to esophageal acid exposure which may correlate symptoms and severity of this disease. By redesigning this valve from grade IV to grade I by means of endoscopic methods or surgery may alleviate the symptoms of in refractory patients. [10, 11]

DEGREE OF ACID EXPOSURE IN VARIOUS GRADES OF GEV[11,12]



Hill et al.[12] stated that by defining the gastro esophageal valve which examined by endoscope seem to be a very good method to assess the acid reflux.

They insisted the correlation between the altered gastro esophageal valve and the positive acid reflux and also its complications. Mechanically defective sphincters are due to alteration of GEV which alters the LES length and pressure.

Hence they concluded that the degree of esophageal acid exposure is linearly correlated with alteration of the gastro esophageal valve.

Haruka Kaneyama[13] et.al stated that GEV contributes the protective mechanism against acid reflux. Gastro esophageal valve has been proposed as a useful tool which predict of gastro esophageal reflux disease.And they have demonstrated that the protective mechanism of this flap valve functions effectively, even in patients with large hiatal hernias.

T. Ismail et. al[14] studied the GEV appearance by endoscopy, grades of distal esophagitis and the yield pressure (YP). He found a good correlation between yield pressure and the valve grading and low yield pressure and esophagitis grading well correlated with abnormal valves. These valves have a major role in esophageal competence at cardia.

Ji Hyun Kim et.al [15] found that the endoscopic visualisation of columnar-lined esophagus(CLE) were more common in obese people, Hiatal Hernia, older age, male gender, erosive esophagitis and abnormal gastro esophageal valve . They revealed the possible causation of CLE and abnormal gastro esophageal valve which may result positive acid reflux.

24-hour ambulatory pH monitoring is considered as gold standard in diagnosing the presence of abnormal reflux.

Pre procedural manometry has to be done to identify the lower esophageal sphincter.

A catheter with pH probe is placed through the nostril. Tip of catheter is placed at 5cm above the lower esophageal sphincter and two more probes one in stomach and 15 cm above the LES are placed.

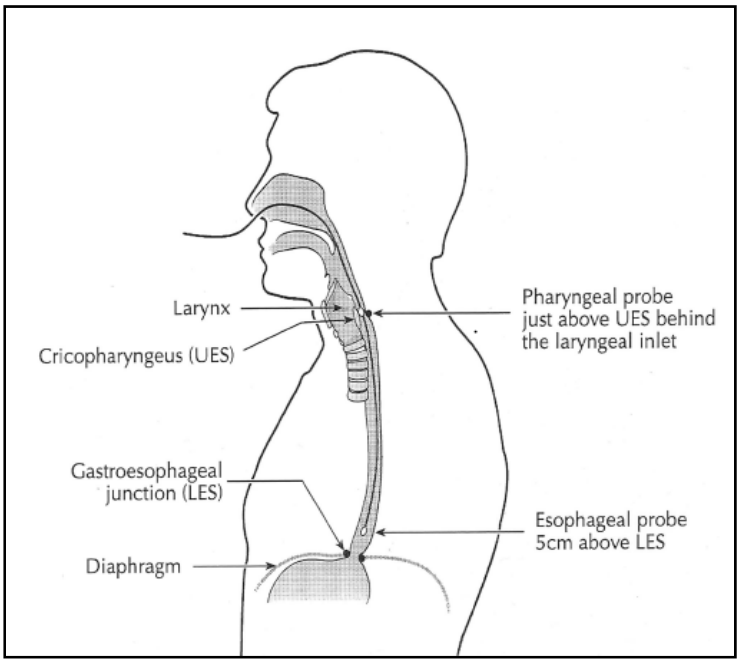
Every 4 to 6 seconds, the pH probe measures the acid exposure and quantifies the amount of exposure.

The patients have to maintain the diary regarding the time of meal, symptoms, symptoms related with meal, symptoms according to positional variation. Ideally pH monitoring should be done for 24hours.

Multiple parameters are calculated. These include percent of time pH < 4, total time of pH <4, percent time on supine position, number of reflux episodes, reflux episode which persist more than 5 minutes and composite score (DeMeester score). It is obtained by combining these results.

DeMeester score of less than 14 have seen in most of the normal individual. DeMeester score consider as a relative scale hence there is no clear cut point which defines the pathologic reflux ([16, 17])

24 HOUR pH MONITORING



The indications for 24 hour ambulatory pH monitoring are ([18, 19, and 20])

i. Symptoms of reflux but fail to respond to optimal dose of a PPI therapy with adequate duration.

ii. In refractory symptoms even with optimal dose of PPI or patients not tolerating the long duration of PPI in whom anti-reflux surgery is contemplated.

iii. Patients with persistent symptoms despite of anti-reflux surgery.

BOR-RU LIN et.al[21] found that the higher grade of gastro esophageal valve was considered as one of the risk factor for erosive esophagitis in Taiwanese patients. Hence grading of gastro esophageal valve examined by endoscopy is well correlated with association of symptoms of GERD, especially in patients with erosive esophagitis.

Fujiwara *et al*.[22] proved in people in Japan the possible correlation of gastro esophageal valve and symptoms of GERD.

S.O ¨ berg et.[23]al concluded that there is a close association between the altered gastro esophageal valve and the positive acid reflux which contributed the GERD related complication.

Hence gastro esophageal valve grading done by endoscopic examination may provide the details of pathological reflux but it is less sensitive than esophageal mucosal injury such as erosive esophagitis. It may be used as a complementary test along with pH monitoring in patient's evaluation with refractory symptoms.

BECKER et. al[24] stated that 40% of the patients with refractory symptoms even with acid suppression therapy may diagnosed by impedance pH monitoring. Patients with pathological reflux are indentified by impedance pH monitoring in refractory GERD may benefited by increasing the dose of PPI therapy which offer higher cure rates.

Hence, pH monitoring combined with impedance manometry (pH/MII) offers more treatment oriented approach in refractory GERD patients.

ChristopHer G et.al[25] concluded pH monitoring is an excellent technique that measures esophageal acid exposure which expressed as a composite score. Composite score seem to be sensitive stool which diagnose the abnormal reflux and also measures the amount of reflux with good specificity

Diagnostic tests for gastro esophageal reflux disease[26]

Test	Sensitivity	Specificity
Barium esopHagogram	40	85
Upper gastro intestinal endoscopy	68	96
Bernstein test	84	83
Ambulatory 24-hour pH monitoring	96	96

Ronnie Fass et.al[27] concluded that 24 hour pH testing has a significant effect on decreasing reflux-provoking activities and may influence the reliability of the test as a physiologic measure of acid reflux.

Surgical management of this disease is evolving very fast and promising mode of treatment for refractory patients. Surgical therapy are indicated in following patients .[28]

- Failure of medical management
- Complications (eg, Barrett esophagus or peptic stricture)
- Patient preference (eg, desiring discontinuation of medical therapy because of quality-of-life concerns, financial concerns, or intolerance to medication)
- Extra esophageal manifestations
- Juvenile esophagitis of long duration without spontaneous remission or refractory to medical management, esophagitis, failure to thrive, or pulmonary compromise
- Mixed and para esophageal hernia, complemented by a gastropexy
- Recurrent reflux or complications after previous anti reflux surgical therapy

Derick J. Christian; MD et.al[29] concluded that surgical methods for GERD are growing fast with more modification which yield good surgical outcome with promising results. Many studies regarding the surgical management of reflux disease are in the progress which may result detailed approach of reflux and pathogenesis of GERD which results better outcome surgical treatment of GERD.

Newer surgical methods such as laparoscopic techniques which decrease the recovery period with promising results may benefit the refractory GERD patients. In laparoscopic era, more focused on the surgery in acid reflux will lighten the treatment in refractory GERD patients.

Huseyin Ayhan Kayaoglu et. al [30] concluded that assessment of OG junction by means of grading of gastro esophageal valve was well correlate with refractory symptoms even after PPI therapy whom required surgical treatment. This valve gave inference in future surgical need in these patients.

In particular, patients with grade 4 valves showed the highest rates of erosive esophagitis and hiatal hernia and frequently underwent surgery for either failed medical management or disease complications.

MATERIALS AND METHODS

This was a cross sectional study which was conducted in department of medical gastroenterology in Rajiv Gandhi Government General Hospital, Chennai, in patients fulfills the inclusion and exclusion criteria.

INCLUSION CRITERIA

1. Patients with refractory symptoms of GERD inspite of 4 weeks of therapy
2. Giving consent

EXCLUSION CRITERIA

1. Patients with poor adherence to PPI therapy
2. Patients continued to take NSAID's
3. Previous history of esophageal or gastric surgery and motility disorder
4. Patients whom seriously ill and not fit for upper GI endoscopy and pH monitoring
5. Not giving consent

All patients with refractory symptoms of GERD, inspite of PPI (omeprazole 20mg twice daily) therapy atleast for 4 weeks were included in this study after convincing the inclusion and exclusion criteria from the period of July 2013 to Feb 2014.

Written consent was obtained from all patients.

All the patients were enquired about the symptomatology, duration of symptoms and duration of PPI therapy and compliance of therapy.

All patients underwent Upper GI endoscopy with 6 hours of fasting with OLYMPUS Upper GI endoscope to look for erosive & non erosive type of GERD, grades of distal esophagitis according to Los Angeles classification and grades of gastro esophageal valve (GEV).

All patients underwent catheter based 24 hour ambulatory pH monitoring

All the patients were instructed to stop proton pump inhibitors (PPI) seven days and Histamine (H_2) antagonists three days before the study.

All patients were on 6hours of fasting before the procedure. Consent was obtained for 24 hour pH monitoring.

Pre procedural manometry was done to locate the esophago gastric junction (OGJ).

pH electrode is placed 5cm above the manometrically determined upper border of the lower esophageal sphincter.

Patients asked to complete a diary during esophageal pH monitoring documenting the timing of meals and symptoms.

Definition used in the study

Symptom evaluation: One day prior to the upper GI endoscopy, patients to be analyzed regarding the presence and frequency of

- Heart burn
- Regurgitation
- Epigastric pain

Refractory symptoms: patients who exhibit partial or lack of response to PPI(omeprazole 20mg) twice daily for duration of 4 weeks

Hill's classification of grading of the gastro esophageal valve (GEV)

- Grade I – prominent fold which closely adherent the endoscope with orientation towards the lesser curvature which closes in all phases of respiration.

- Grade II - less well prominent than grade 1which occasionally opens with respiration

- grade III, no defined tissue around the endoscope which not closes during respiration

- grade IV, always associated with hiatal hernia with no fold where esophageal lumen seen from the fundus

Los Angeles classification distal esophagitis

- Grade A - ≤5 mm one or more mucosal breaks along the mucosal folds

- Grade B - One or more mucosal breaks >5 mm confined to folds but not continuous between tops of mucosal folds

- Grade C - Mucosal breaks continuous between tops of two or more mucosal folds but not circumferential

- Grade D - Circumferential mucosal break

RESULTS

This study included 30 patients with refractory symptom of GERD with proton pump inhibitor therapy (PPI) which include 22(73%) male and 8(27%) female in this which illustrated in figure 1.

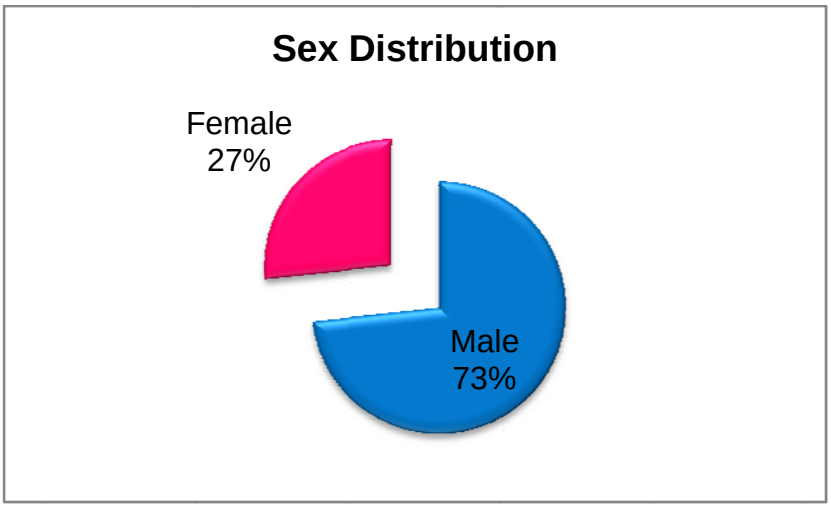


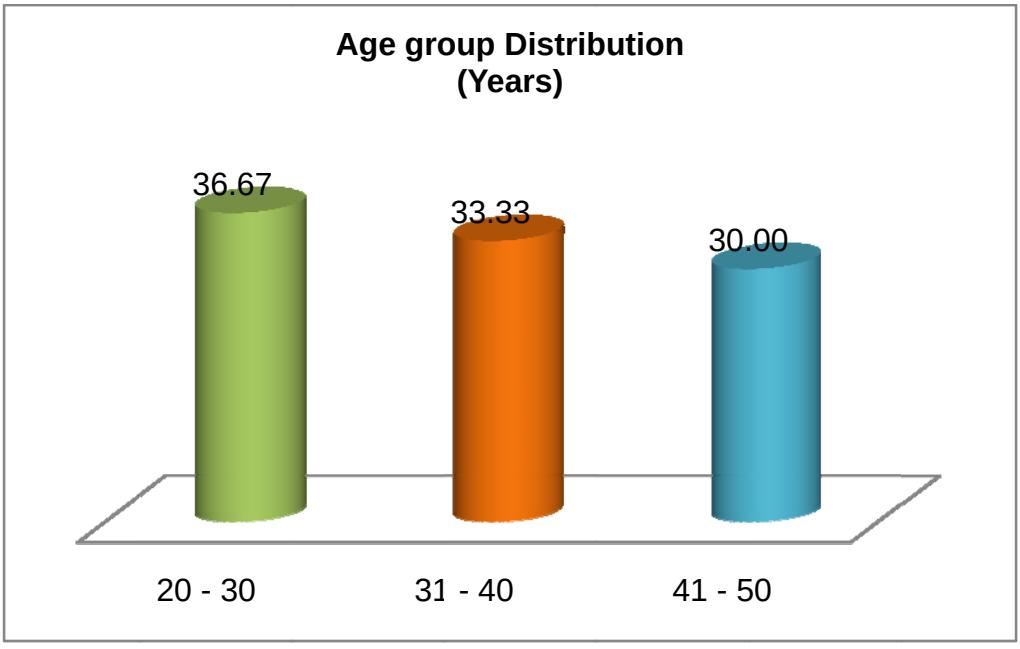
Figure 1

The age group of study population includes 11 patients in between 20- 30years, 10 patients in between 31- 40years and 9 patients in between 41- 50years which illustrated in table 1 and figure 2.

Age Distribution (Table 1)

Age Group (Year)	N	Percentage
20 – 30	11.00	36.67
31 – 40	10.00	33.33
41 – 50	9.00	30.00

Figure 2



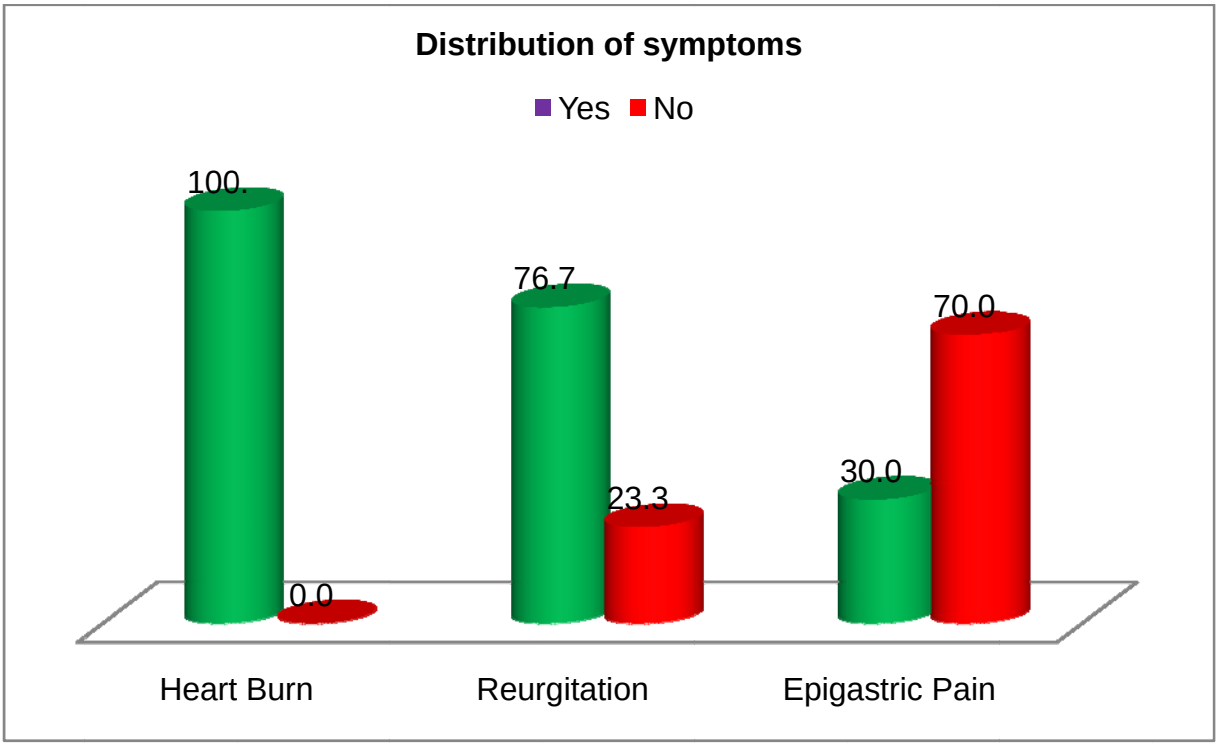
Heart burn was the predominant symptom which present in all patients (100%) followed by regurgitation which present in 76.7% of study population and epigastric pain which present in 30%. This was illustrated in table 2 and figure 3.

Table 2

Percentage of Distribution of symptoms (heart burn, regurgitation, epigastric pain)

Distribution of symptoms	Yes	No
Heart burn	100.0(n=30)	0.0(n=0)
Regurgitation	76.7(n=23)	23.3(n=7)
Epigastric pain	30.0(n=9)	70.0(n=9)

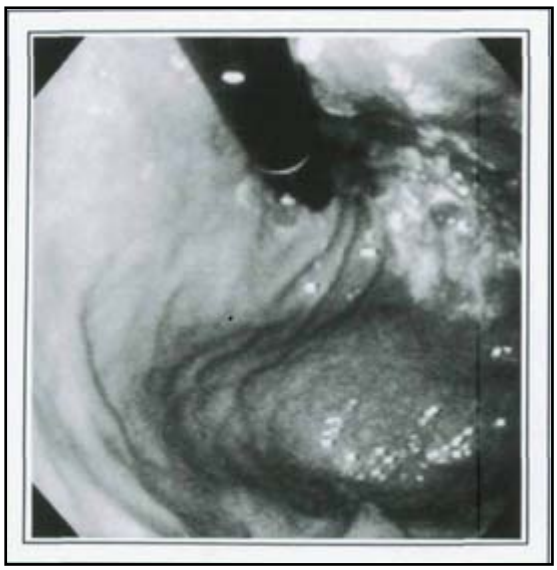
Figure 3



Upper gastrointestinal endoscopy revealed 11(36.7%) persons had grade 1 gastro esophageal valve (GEV), 5 (16.7%) persons had grade 2 GEV, and 8 (26.7%) persons had grade 3 and 6(20%) persons had grade 4 GEV , which was illustrated in table 3 and figure 4.

GRADE 1 GEV

GRADE 2 GEV



GRADE 3 GEV

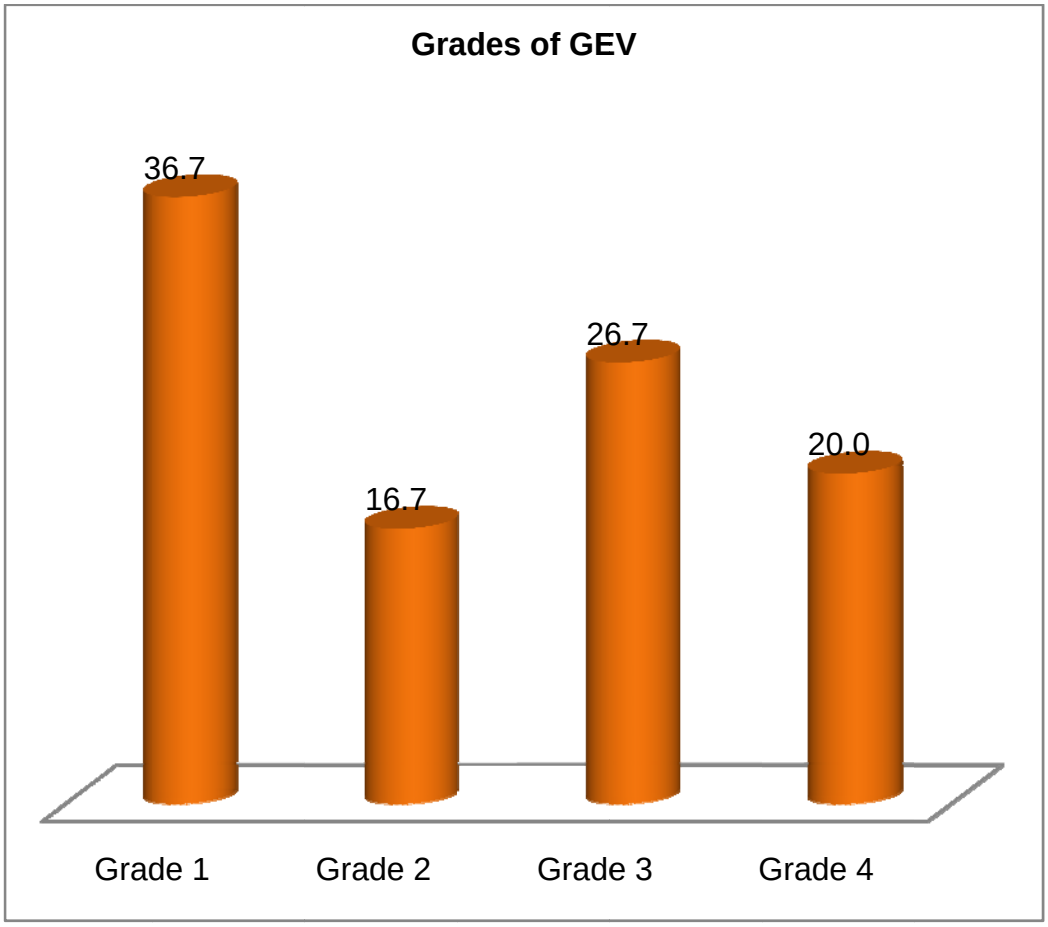
GRADE 4 GEV

Table 3

Percentage of Distribution of grades of Gastro Esophageal Valve

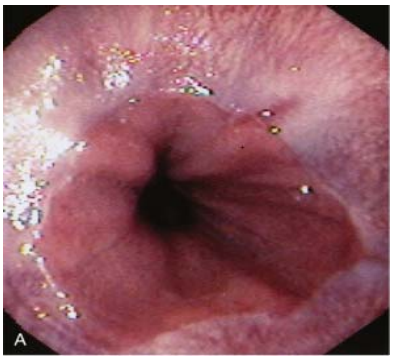
Grades of GEV	N	Percentage
GRADE 1	11.00	36.7
GRADE 2	5.00	16.7
GRADE 3	8.00	26.7
GRADE 4	6.00	20.0

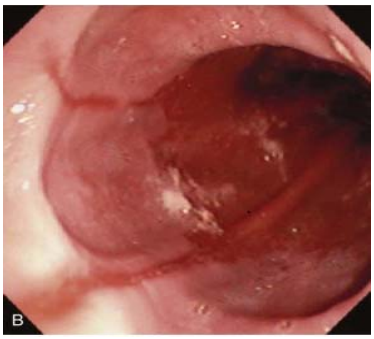
Figure 4



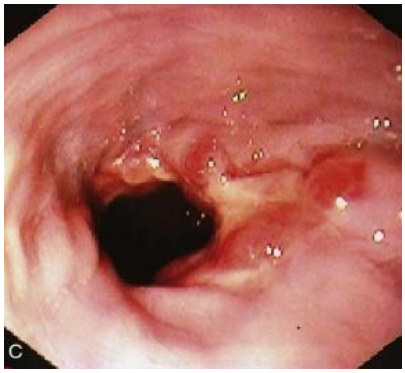
The UGI scopy also revealed 24persons had normal mucosa, 3 persons had grade A distal esophagitis, 2 persons had grade B distal esophagitis, 1 persons had grade C distal esophagitis and none of them had grade D distal esophagitis, which was illustrated in table 4 and figure 5.

Los Angeles classification distal esophagitis





GRADE A DISTAL ESOPHAGITIS **GRADE B DISTAL ESOPHAGITIS**

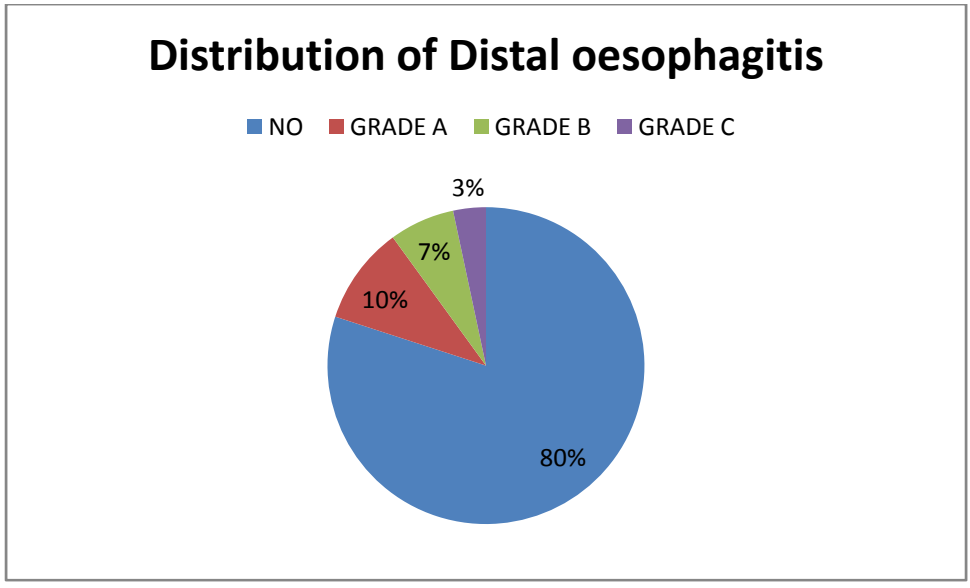


GRADE C DISTAL ESOPHAGITIS

Table 4

Grades of Distal Esophagitis	n	Percentage
NO	24.00	80.00
GRADE A	3.00	10.00
GRADE B	2.00	6.67
GRADE C	1.00	3.33

Figure 5



24 hour ambulatory pH monitoring revealed distribution of percent time < 4 in between 0.40% to 90.90% with a mean of 7.36%, total duration of time pH <4 in minutes between 3 to 1260 with a mean of 89.93 minutes, number of acid reflux episode in between 8 to 334 with a mean of 90.5, number of reflux episode > 5 minutes was seen in 10 persons with a mean of 5.6 and distribution of Demeester score in between 1.5 to 267.8 with a mean of 24.45.

This study found a significant correlation between the grades of gastro esophageal valve (GEV) and presence of distal esophagitis which shown in table 5 and figure 6.

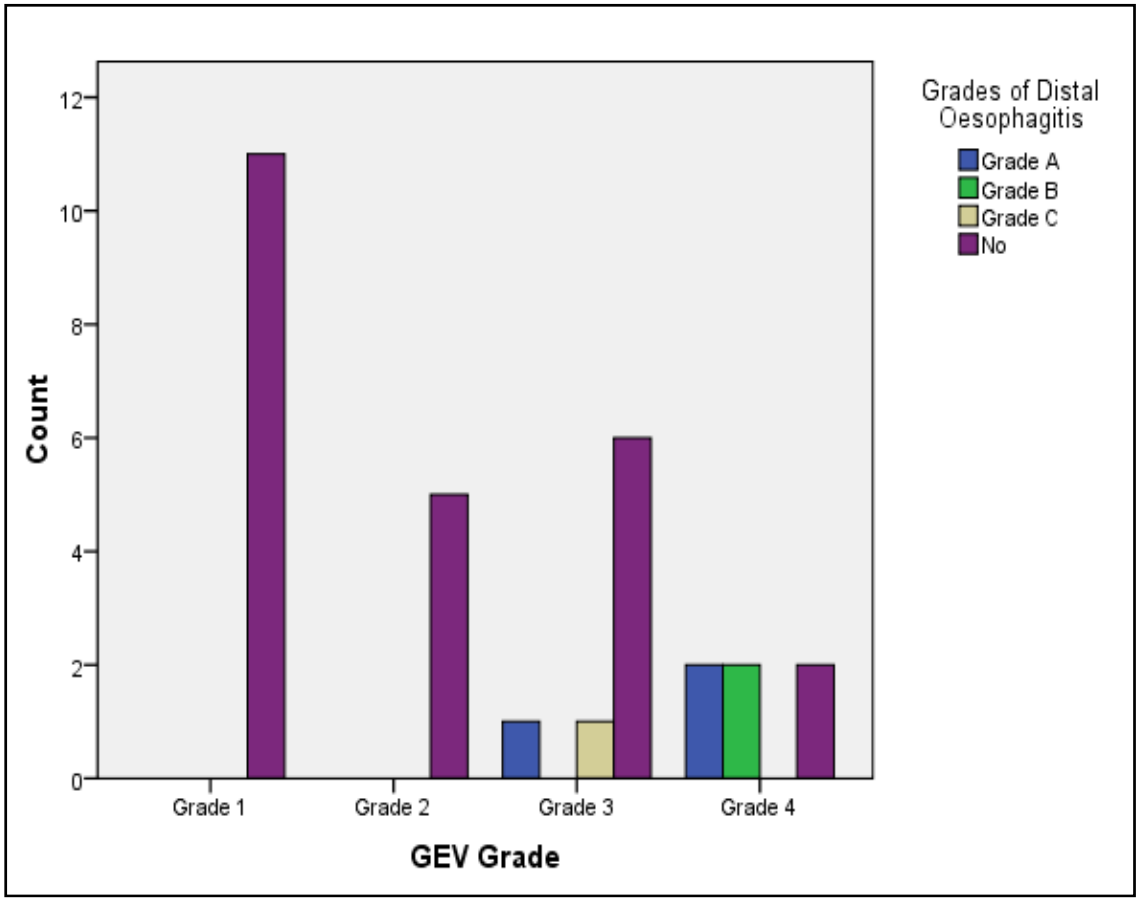
Abnormal gastro esophageal valve (grade 3 and grade 4) was associated significant number of distal esophagitis. But there was no correlation found between grades of gastro esophageal valve and grades of distal esophagitis.

Grades GEV and Grades of Distal Esophagitis Cross tabulation

Table 5

Grades of GEV	Grades of Distal Esophagitis				Total
	Grade A	Grade B	Grade C	No	
Grade 1	0	0	0	11	11
Grade 2	0	0	0	5	5
Grade 3	1	0	1	6	8
Grade 4	2	2	0	2	6
Total	3	2	1	24	30

Figure 6



This study found a significant correlation between significant acid reflux which defined as percent time pH < 4 is more than 5% and grades of gastro esophageal valve. Abnormal gastro esophageal valve (grade 3 and grade 4) was associated with significant number of positive acid reflux.

For correlation, mean plots were used to study the variation in the mean values of total time esophageal pH (percentage) between different grades of gastro esophageal valve.

It can inferred from the plot that study subjects with GEV Grade 1 showed lowest mean value in the group for percentage total time esophageal pH<4 (Mean=2.9, SD=5.7, N=11).

On the other hand study subjects from the GEV Grade 3 had the highest mean value in the group for percentage total time esophageal pH<4 when compared to the grades of other groups (Mean=16.0, SD=30.4, N=8).

The study identified that the subjects with GEV Grade 2 had the mean value of percentage total time esophageal pH<4 (Mean=3.7, SD=5.2, N=5).

While the study subjects with GEV Grade 4 had the mean value (Mean=8.9, SD=4.3, N=6) for percentage total time esophageal pH<4 which shown in table 6, figure 7and figure 8.

Table 6

GEV Grade	N	Mean	Std. Deviation
Grade 1	11	2.9	5.7
Grade 2	5	3.7	5.2
Grade 3	8	16.0	30.4
Grade 4	6	8.9	4.3
Total	30	7.7	16.6

Figure 7

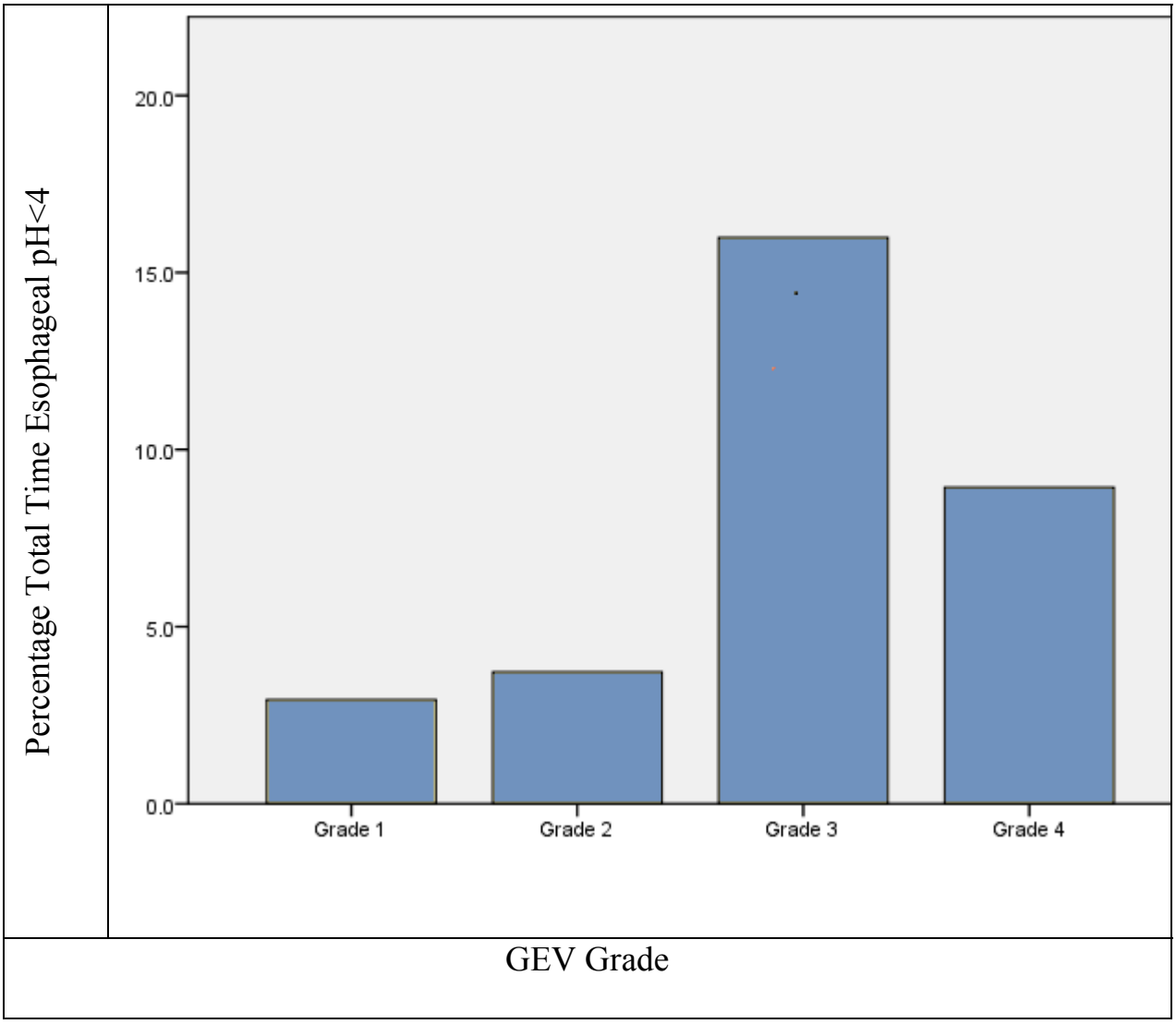
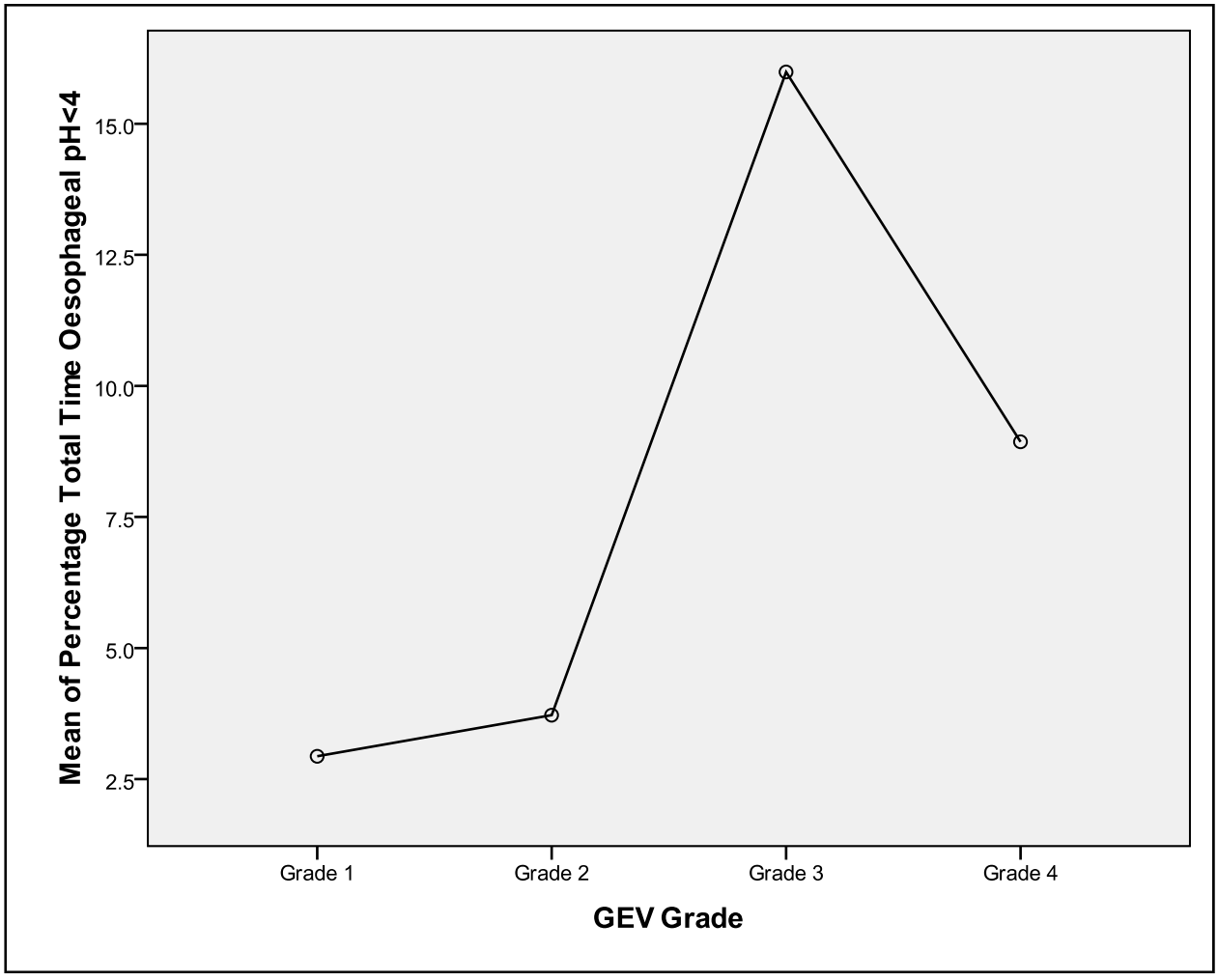

Percentage Total Time Esophageal pH<4
20.0
15.0
10.0
5.0
0.0
Grade 1
Grade 2
Grade 3
Grade 4
GEV Grade

Figure 8


Mean of Percentage Total Time Oesophageal pH<4
15.0
12.5
10.0
7.5
5.0
2.5
Grade 1
Grade 2
Grade 3
Grade 4
GEV Grade

This study found a significant correlation between significant acid reflux which defined as Demeester score of >14.7 and grades of gastro esophageal valve. Abnormal gastro esophageal valve (grade 3 and grade 4) was associated with higher Demeester score compared to normal gastro esophageal valve (grade 1 and grade 2).

For correlation, mean plots were used to study the variation in the mean values of Demeester score between different grades of gastro esophageal valve.

It can inferred from the plot that study subjects with GEV Grade 1 showed lowest mean value in the group for Demeester score (Mean= 5.8, SD=3.5, N=11). On the other hand study subjects from the GEV Grade 3 had the highest mean value in the group for Demeester score when compared to the grades of other groups (Mean= 50.3, SD= 88.2, N=8).

The study identified that the subjects with GEV Grade 2 had the mean value of Demeester score (Mean=8.1, SD=2.9, N=5).While the study subjects with GEV Grade 4 had the mean value (Mean=37.8, SD=21.8, N=6) for Demeester score which shown in table 8, table 9, figure 9, figure 10 and figure 11.

Table 8

DeMeester Score			
GEV Grade	Mean	N	Std. Deviation
Grade 1	5.8	11.0	3.5
Grade 2	8.1	5.0	2.9
Grade 3	50.3	8.0	88.2
Grade 4	37.8	6.0	21.8
Total	24.5	30.0	48.6

Table 9

DeMeester Score > 14.7			
GEV Grade	Mean	N	Std. Deviation
3.0	72.7	5.0	109.3
4.0	37.8	6.0	21.8
Total	53.7	11.0	73.1

Figure 9

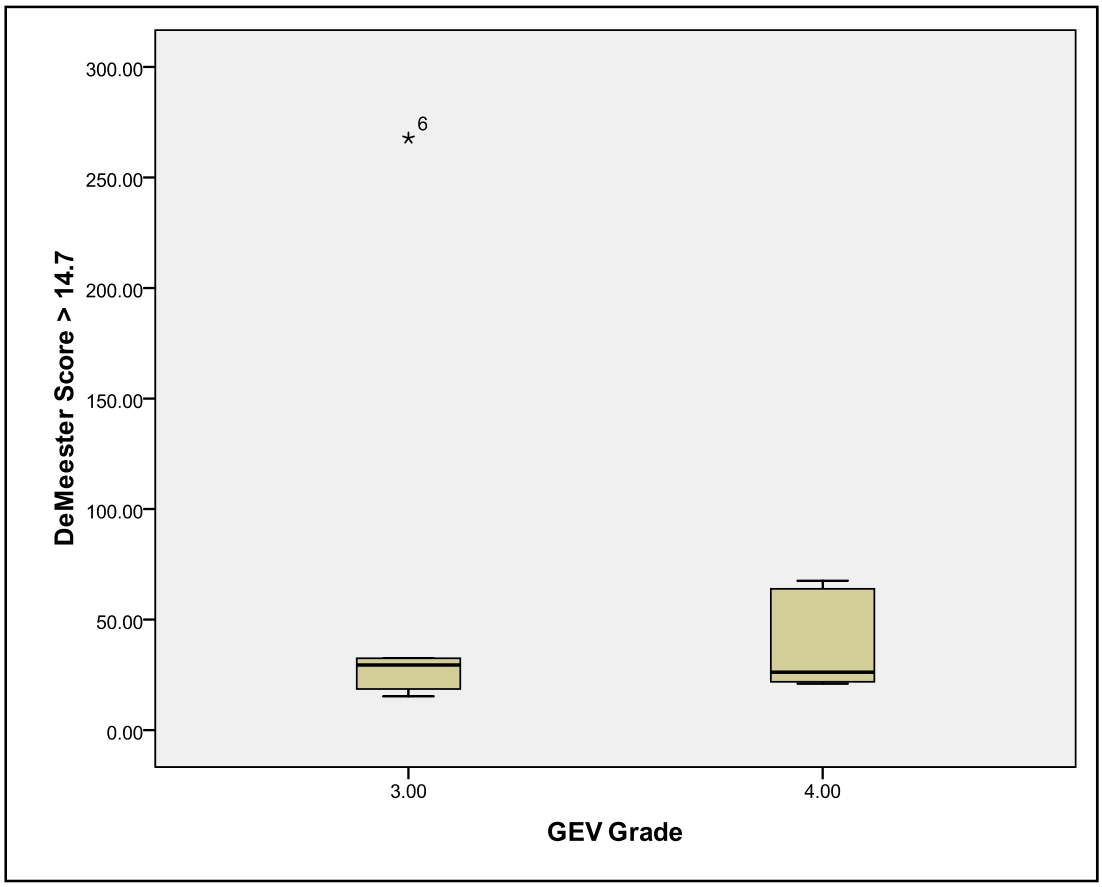

DeMeester Score > 14.7
300.00
250.00
200.00
150.00
100.00
50.00
0.00
6
3.00
4.00
GEV Grade

Figure 10

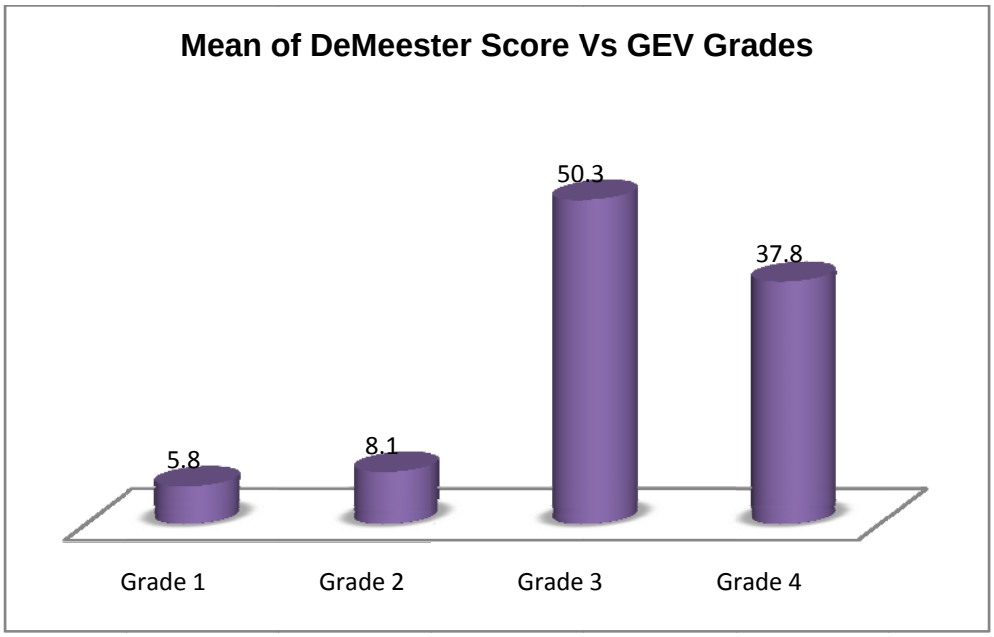
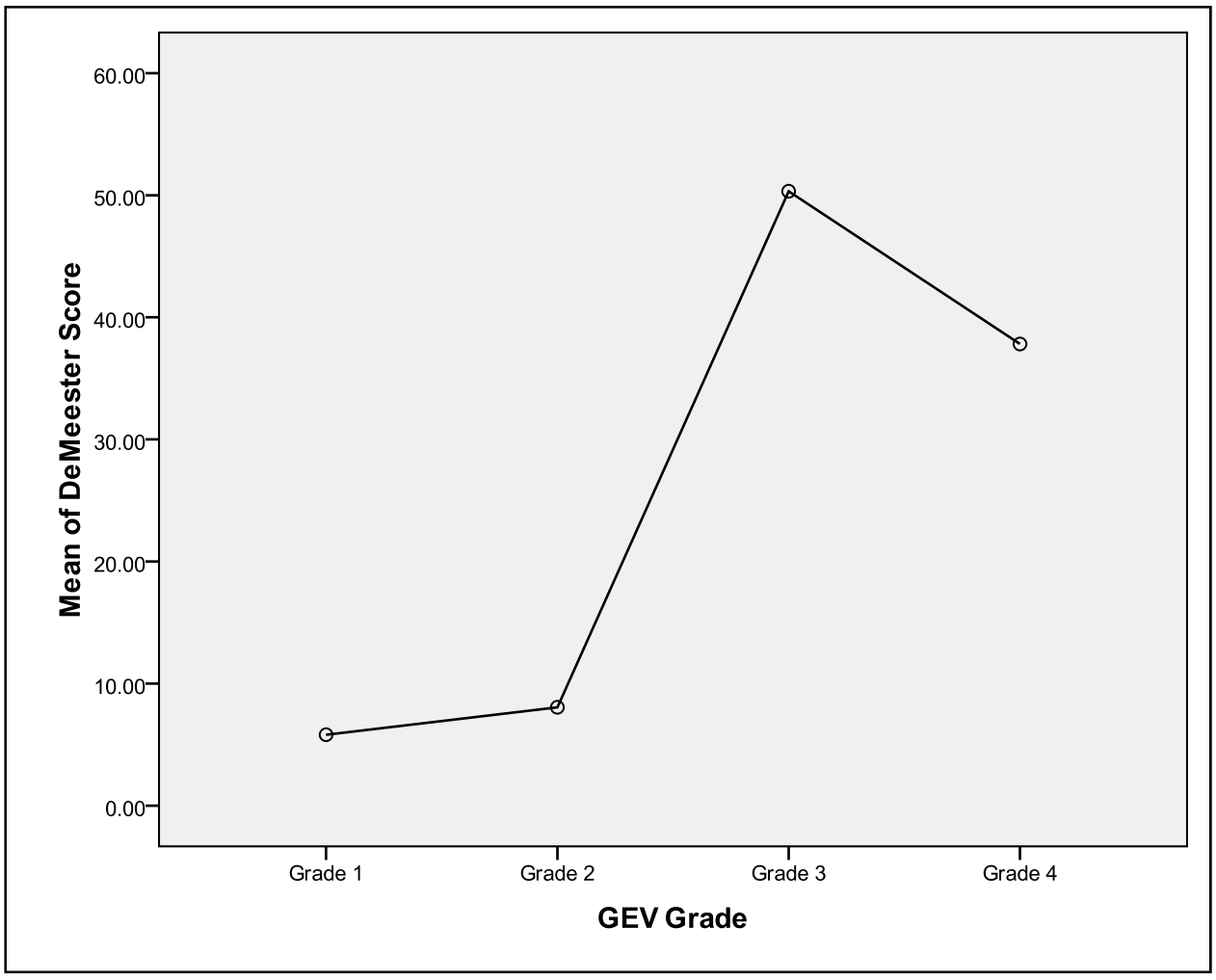

Mean of DeMeester Score Vs GEV Grades
5.8
8.1
50.3
37.8
Grade 1
Grade 2
Grade 3
Grade 4

Figure 11


60.00
50.00
40.00
30.00
20.00
10.00
0.00
Mean of DeMeester Score
Grade 1
Grade 2
Grade 3
Grade 4
GEV Grade

DISCUSSION

This study showed that grades of gastro esophageal valve is a independent factor which may predict the response to proton pump inhibitor (PPI) therapy, relapse of symptoms and GERD related complication such as distal esophagitis.

The prevalence of grades of gastro esophageal valve (GEV) in this study population were grade 1- 36.7 %(11), grade 2- 16.7 %(5), grade 3- 26.7 %(8) and grade 4-20%(6) as compared to study conducted by S.O berg et.al[23] who showed the prevalence of GEV as follows, grade 1-16%(43),grade 2-22(57), grade 3-26%(71) and grade 4-36%(97). The prevalence of GEV in both the study is similar.

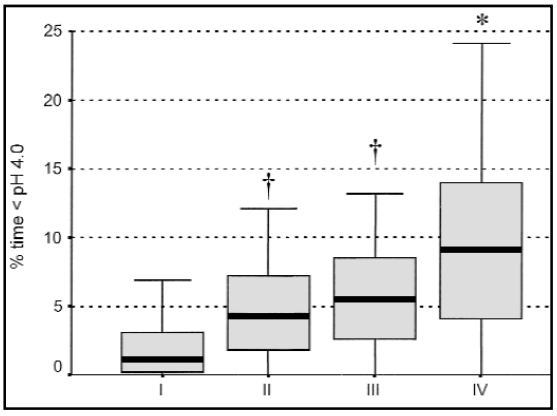
This study revealed abnormal acid reflux as evidenced by 24hour pH monitoring (percent time pH < 4 was more than 5% and Demeester score more than 14.7) seen in 11(36.6%) patients in the range between 5.10% to 90.90% and 19(63.3%) patients had normal acid reflux in the range between 0.40% to 3.70%.

This study identified the percent of time pH <4in various grades GEV as following, Grade 1valve - mean 2.9, SD of 5.7, grade 2-mean of 3.7 , SD 5.2, grade 3- mean 16.0,SD 30.4 and grade 4- mean 8.9, SD 4.3.

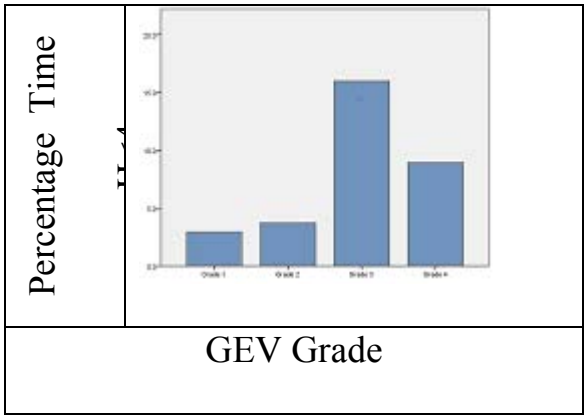
These finding suggested that the patients with grade 3 and grade 4 GEV had significant number of abnormal acid reflux.

Compared with the study done by S.O berg et.al[23] who found that abnormal acid exposure as evidenced by percentage of time pH less than 4.0 in various grades of GEV to be as follows, grade 1 had mean value of 1, grade 2 had mean value 4, grade 3 had mean value of 6 and grade 4 had mean value of 9.

But in this present study mean value in grade 3 was higher than grade 4(16 Vs 8.9).



S.OBERG et.all



PRESENT STUDY

This study also found the incidence of distal esophagitis in various grades of GEV as follows, grade 1- 0% , grade 2 – 0% , grade 3- 25% and grade 4 – 66% .

Compared with study done by S.O berg et.al[23], the incidence of distal esophagitis was more with higher grade of GEV than grade 1 and grade 2 GEV. The incidence of distal esophagitis was grade 1- 0%, grade 2- 15.8%, grade 3-18.3% and grade 4- 27.8%.

They also noted the incidence of distal esophagitis in grade 2 GEV which was not seen in the present study.

The same inference found by BOR-RU LIN et.al[21]and he showed that 41.3% (*n*=209) patients had GERD and 24.7% (n=125) had erosive esophagitis. Out of these >25% had higher grade of GEV. The incidence of distal esophagitis in grade 3 and grade 4 were 40.7% and 52%. And he concluded that Endoscopic grading of the GEV is well correlated with association of GERD, and in particular erosive esophagitis (EE).

Ji Hyun Kim, M.D.et.al[15] also found that higher grade of gastro esophageal valve associated with more incidence of erosive esophagitis. His study showed the incidence of distal esophagitis as follows, grade 1-2.5%, grade 2- 8.3%, grade 3 - 17.5% and grade 4- 27%.

GRADES OF GEV		**3**	**4**
INCIDENCE OF DISTAL ESOPHAGITIS (%)	**S.OBERG et.al**	**18.3**	**27.8**
	BOR-RU LIN et.al[21]	**40.7**	**52.0**
	Ji Hyun Kim, M.D.et.al[15]	**17.5**	**27**
	PRESENT STUDY	**25**	**66**

These findings are confirmed by study done by T. Ismail et.al[14] concluded that increased abnormality of the gastro esophageal valve was associated with all grades of esophagitis and with a low yield pressure (YP) and author concluded that valve mechanism at the cardia has an important role in determining its competence.

Huseyin Ayhan Kayaoglu et.al[30] stated that higher grades of GEV grade had more significant acid exposure and more incidences of erosive esophagitis compared lower grade valves ($p < 0.001$). 63.6 % of the grade 4 gastro esophageal valve patients underwent surgery for various indications ($p < 0.001$). Patients with grade 4 gastro esophageal valves showed the highest rates of erosive esophagitis and frequently underwent surgery for either failed medical management or disease complications.

This study also revealed abnormal gastro esophageal valve (grade 3 & grade 4) associated with increased incidence of distal esophagitis. On long term follow up, abnormal gastro esophageal valve may predict the complications of GERD.

24 hour ambulatory pH monitoring is considered as an important investigation in evaluation of GERD patients. This study correlated the grades of gastro esophageal valve with symptomatology, incidence of distal esophagitis and 24 hour pH ambulatory monitoring findings. Most of the other studies have not included 24 hour pH ambulatory monitoring.

In this study, abnormal GEV (grade 3 & grade 4) had high value in 24 hour pH monitoring percentage of time pH < 4 and Demeester score) than normal gastro esophageal valve (grade 1 & grade 2). This difference was statistically significant.

This study showed high value of 24 hour pH monitoring finding in grade 3 GEV than grade 4. Further studies using more number of patients will better illustrate the efficacy of 24hour pH monitoring.

CONCLUSION

Presence of abnormal gastro esophageal valves which are detected by retro flexion of upper GI endoscopy may predict the positive esophageal acid exposure and complication such as erosive esophagitis.

And also gastro esophageal valve may predict the response to proton pump inhibitor therapy (PPI). Patients with abnormal gastro esophageal valves (grade 3& grade 4) may have refractory symptoms even after PPI therapy compared with patients with normal gastro esophageal valve ((grade 1 & grade 2).

But it requires study with large population needed to substantiate these results.

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PROFOMA

NAME: AGE: SEX:

PLACE:

SYMPTOMS:

- HEART BURN
- REURGITATION
- EPIGASTRIC PAIN

DURATION OF SYMPTOMS: _____

FREQUENCY OF SYMPTOMS: _____

PPI DOSE AND DURATION _____

CO MORBID ILLNESS: YES- NO- IF YES, DIGNOSIS AND DURATION

_____

INVESTGATIONS: HEMOGLOBIN- TC- PLATELET COUNT-

RBS- BLOOD UREA- S.CREATININE-

OGD SCOPY:

- EROSIVE-
- NON EROSIVE
- TYPE OF GEV

24hr pH MONITORING:

- Percent time pH <4
- Number reflux episode
- Number reflux episode persist >5miutes
- Demeester score

NAME	AGE	SEX	HEART BURN	REURGITATION	PIGASTRIC PAI	URATION OF I	OGD SCOPY	TYPE OF GE	MONITORING FINDINS				
						DISTAL ESOPHAGITIS			PERCENT TIME pH < 4	TIME pH <4	REFLUX EPISODE	EPISODE > 5MIN	DEEMEESTER SCORE
SUBASH	24	1	YES	NO	NO	6WEEKS	NO	GRADE 2	1.30%	18	36	0	6.3
SHANTHI	37	2	YES	YES	NO	12WEEKS	NO	GRADE 3	2.20%	31	60	1	11.5
MAHALINGAM	45	1	YES	YES	YES	8WEEKS	NO	GRADE 1	1.90%	28	52	0	7.8
THIRUMALAI	28	1	YES	YES	NO	12WEEKS	NO	GRADE 1	0.60%	9	23	0	3.7
SATHIYAN	27	1	YES	YES	NO	6WEEKS	GRADE A	GRADE 3	3.70%	53	69	1	15.3
VIGNESH	20	1	YES	YES	YES	12WEEKS	GRADE B	GRADE 4	6.60%	104	165	0	26.2
SHAKIRA	46	2	YES	YES	YES	20WEEKS	GRADE A	GRADE 4	6.10%	88	84	1	21.9
PRABHU	35	1	YES	YES	NO	6WEEKS	NO	GRADE 1	2%	29	73	0	9.7
BHOOPALAN	41	1	YES	YES	YES	12WEEKS	NO	GRADE 4	15.80%	220	334	4	67.6
ARUL	34	1	YES	NO	YES	20WEEKS	GRADE B	GRADE 4	12.90%	187	229	6	63.9
RAMKUMAR	37	1	YES	YES	NO	12WEEKS	GRADE C	GRADE 3	90.90%	1260	237	34	267.8
AJAY KUMAR	22	1	YES	NO	NO	20WEEKS	NO	GRADE 1	0.40%	5	25	0	3.2
ANURATHA	39	2	YES	NO	NO	12WEEKS	NO	GRADE 1	1%	15	38	0	4.9
AROKIYAATHAN	39	1	YES	NO	YES	12WEEKS	NO	GRADE 4	5.10%	67	144	0	21.1
ARUN KUMAR	26	1	YES	NO	NO	20WEEKS	NO	GRADE 1	0.70%	10	27	0	3.8
BANU	33	2	YES	YES	YES	24 WEEKS	NO	GRADE 3	8.40%	115	255	3	29.5
BRITTO	33	1	YES	YES	NO	20WEEKS	NO	GRADE 3	3%	44	80	0	14
KARTHICK	38	1	YES	YES	NO	36WEEKS	NO	GRADE 2	1.40%	20	54	0	9
ARINDAM	30	1	YES	YES	NO	20WEEKS	NO	GRADE 1	1.10%	16	17	0	5.3
ABDUL RAHIM	25	1	YES	YES	NO	20WEEKS	NO	GRADE 1	2.70%	37	79	0	13.2
KANNAN	41	1	YES	YES	NO	12WEEKS	NO	GRADE 3	3.60%	51	78	0	13.4
SURYA	44	2	YES	YES	NO	20WEEKS	NO	GRADE 1	1.30%	18	41	0	8.2
MAHENDRAN	29	1	YES	NO	NO	20WEEKS	NO	GRADE 2	0.60%	8	41	0	4.5
NARAYANAN	42	1	YES	YES	YES	24 WEEKS	GRADE A	GRADE 4	7.10%	92	163	3	26.2
VAEETHA KANN	47	1	YES	YES	NO	24 WEEKS	NO	GRADE 3	7.90%	109	153	2	32.5
MA MAHESWA	41	2	YES	YES	NO	20WEEKS	NO	GRADE 1	20.00%	3	8	0	1.5
KANNABIRAN	41	1	YES	YES	NO	20WEEKS	NO	GRADE 2	2.40%	6	15	0	12.2
SAKTHIVEL	27	1	YES	YES	NO	24 WEEKS	NO	GRADE 3	8.20%	35	96	1	18.6
KUMARI	36	2	YES	YES	YES	24 WEEKS	NO	GRADE 1	0.60%	5	15	0	2.6
VANI	24	2	YES	YES	NO	20WEEKS	NO	GRADE 2	1.20%	15	24	0	8.3

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI –3

EC RegNo:ECR/270/Inst./TN/2013 Telephone No : 04425305301
Fax : 044 25363970
Date:10.09.2013

CERTIFICATE OF APPROVAL

To
Dr.G.Rajesh Kumar,DM(MGE)Post Graduate,
Department of Medical Gastroenterology,
Madras Medical College, Chennai-3.

Dear Dr.G.Rajesh Kumar,

The institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled "Correlation of gastroesophageal valve, symptomatology and 24 hour ph monitoring in gerd patients with refractoy wymptoms in South India-Across sectional study " No.07092013.

The following members of Ethics Committee were present in the meeting held on 10.09.2013 conducted at Madras Medical College, Chennai -3.

1. Dr.G.SivaKumar, MS FICS FAIS --- Chairperson
2. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
3. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
4. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
5. Prof. Kalai Selvi -- Member
   Prof of Pharmacology, MMC, Ch-3
6. Prof. Siva Subramanian, -- Member
   Director, Instt. of Internal Medicine, MMC, Ch-3
7. Thiru. S. Govindsamy, BABL -- Lawyer
8. Tmt. Arnold Saulina MA MSW -- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandhini

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
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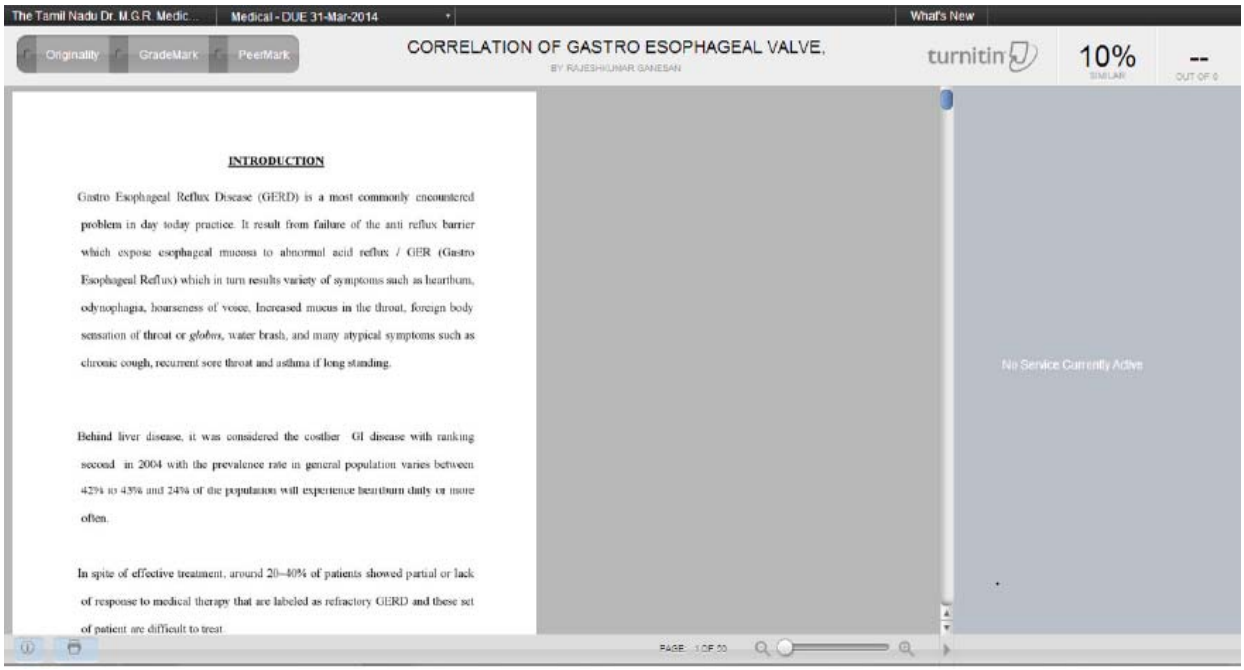
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OUT OF 0
INTRODUCTION
Gastro Esophageal Reflux Disease (GERD) is a most commonly encountered problem in day today practice. It result from failure of the anti reflux barrier which expose esophageal mucosa to abnormal acid reflux / GER (Gastro Esophageal Reflux) which in turn results variety of symptoms such as heartburn, odynophagia, hoarseness of voice, Increased mucus in the throat, foreign body sensation of throat or globus, water brash, and many atypical symptoms such as chronic cough, recurrent sore throat and asthma if long standing.
Behind liver disease, it was considered the costher GI disease with ranking second in 2004 with the prevalence rate in general population varies between 42% to 43% and 24% of the population will experience heartburn daily or more often.
In spite of effective treatment, around 20–40% of patients showed partial or lack of response to medical therapy that are labeled as refractory GERD and these set of patient are difficult to treat.
No Service Currently Active
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Information sheet

We are conducting a study on "CORRELATION OF GASTRO ESOPHAGEAL VALVE, SYMPTOMATOLOGY AND 24 HOUR PH MONITORING IN GERD PATIENTS WITH REFRACTORY SYMPTOMS IN SOUTH INDIA – A CROSS SECTIONAL STUDY" at The Department of Medical Gastroenterology, Rajiv Gandhi Govt. General Hospital, Chennai. The purpose of the study is to correlation of gastro esophageal valve, symptomatology and 24 hour ph monitoring in gerd patients with refractory symptoms.

The privacy of the patients in this research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the study may be intimated to you at the end of the study period or during the study if anything is found abnormal. This may aid in the management or treatment.

Signature of Investigator

Signature of participant

Date:

CONSENT

DESCRIPTION: You are invited to participate in a research study on Correlation of gastro esophageal valve, symptamatology and 24 hour pH monitoring in GERD patients with refractory symptoms in south India – A cross sectional study

PROCEDURES: You will be asked to undergo upper GI endoscopy and 24 hour pH monitoring. It requires fasting for atleast 6 hours,procedure will not require any sedation.
RISKS AND BENEFITS: Risks include slight abdominal discomfort and very rarely aspiration. It will help to assess the duration of medical treatment and help in predicting need for endoscopic therapy and surgery in the future.

TIME INVOLVEMENT: Your participation in this study will be same as the time taken for management of GERD.

PAYMENTS: You will not be paid to participate in this study.

I, _____ , hereby consent to undergo upper GI endoscopy and 24hr pH monitoring for the purpose of indentifying type of GEV and estimation acid reflux. I understand the risks and benefit of the procedure. I have understood that the findings will be used for research and the results will not be available to me.

Signature of the patient

Name of the Patient

Witness – Signature, Name and address